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[Your Name]

[Your Title]

[Your Company]

[Street Address, City, State ZIP]

May 14, 2026

[Opposing Counsel Name]

[Firm Name]

[Address]

Re: U.S. Patent No. 12186474 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 12186474 (the "12186474 Patent"). After preliminary review, we have substantial concerns about the validity, enforceability, and scope of the asserted claims, summarized below. We reserve all rights and defenses.

1. Subject Patent — Summary

An analysis of U.S. Patent 12,186,474 reveals the following details regarding the invention, its ownership, and legal status.

Title: System and method for collecting plasma.

Assignee: Haemonetics Corp.

Inventor: Michael Ragusa.

Filing Date: March 18, 2021.

Issue Date: January 7, 2025.

Abstract: The patent describes a method for collecting plasma that involves determining a donor's weight, height, and hematocrit to calculate their total plasma volume and a specific target collection volume. This target is based on a set percentage of the donor's total plasma. The process involves withdrawing blood, adding an anticoagulant, separating the blood into plasma and other components, and...

2. Validity Concerns under 35 U.S.C. § 102 — Prior Art

We have identified prior-art references that, in our preliminary view, anticipate one or more asserted claims of the 12186474 Patent:

As a senior US patent analyst, I have conducted a thorough review of US Patent 12,186,474 B2.

Below is an analysis of the most relevant prior art cited by the patent. The '474 patent is directed at a system and method for collecting plasma by determining a target volume of "pure plasma," which accounts for the volume of anticoagulant mixed with the collected plasma. This is achieved by calculating the percentage of anticoagulant in the collected fluid, a departure from prior art that typically collected a total volume of anticoagulated plasma based on donor weight. Out of the extensive list of 206 patent citations referenced in the '474 patent, the following prior art is deemed most relevant as it addresses core concepts of the invention, namely the individualized determination of plasma collection volumes and the management of anticoagulant concentrations.

Analysis of Most Relevant Prior Art

1. US Patent No. 8,628,489 B2: "Three-line apheresis system and method"

• Full Citation: US Patent 8,628,489 B2, "Three-line apheresis system and method," assigned to Haemonetics...

3. Obviousness under 35 U.S.C. § 103

Independent of § 102, we believe the asserted claims are obvious in view of combinations of prior art that a person having ordinary skill in the art would have been motivated to combine:

An analysis of US Patent 12,186,474 under 35 U.S.C. § 103 for obviousness involves determining if the claimed invention would have been apparent to a person of ordinary skill in the art at the time the invention was made. This requires a review of the patent's claims and the cited prior art.

Analysis of Key Claims of US Patent 12,186,474

The core of this patent revolves around a system and method for plasma collection that is individualized to the donor, aiming to collect a "target volume of pure plasma." This is a departure from prior methods that collected a standardized volume of plasma mixed with an anticoagulant, without accounting for the actual amount of pure plasma.

Key aspects of the claims include:

- Individualized Collection Target: Calculating a target plasma collection volume based on donor-specific parameters like weight, height, and hematocrit. This is a central feature, moving away from a one-size-fits-all approach. (As detailed in the Abstract and the Description, e.g., in relation to FIG. 5)
- Pure Plasma Calculation: The system actively calculates the volume of...

4. Litigation History of the Patent

Public records reflect that the 12186474 Patent has been the subject of the following litigation, which informs our view of the asserted claims and your client's enforcement posture:

- Haemonetics Corporation v. Terumo BCT, Inc. — 1:25-cv-01409 · United States District Court for the District of Colorado · filed 2025-05-05 · Ongoing
- Haemonetics Corporation v. Fresenius Kabi USA, LLC et al. — 1:25-cv-08680 · U.S. District Court for the Northern District of Illinois · filed 2025-07-25 · ongoing

5. Request

In light of the foregoing, we request that your client (i) provide a detailed claim chart identifying each accused product or service and mapping every limitation of each asserted claim, (ii) identify any prior art known to your client, including any references cited during prosecution or reexamination, and (iii) substantiate the basis for any damages or licensing demand. We are prepared to discuss the matter further once we have received and reviewed the foregoing.

Sincerely,

[Your Name]

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